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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,617	03/10/2004	Chi-Huey Wong	TSRI 696.1 D1	6187
26621	7590	01/18/2006	EXAMINER	
THE SCRIPPS RESEARCH INSTITUTE OFFICE OF PATENT COUNSEL, TPC-8 10550 NORTH TORREY PINES ROAD LA JOLLA, CA 92037			FREISTEIN, ANDREW B	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,617

Applicant(s)

WONG ET AL.

Examiner

Andrew B. Freistein

Art Unit

1626

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 24-26 are currently pending in the instant application. Claims 1-23 were cancelled by amendment.

Priority

This application is a Divisional of US Application No. 09/980,869, filed 02/12/2002, which granted as US Pat. No. 6,774,140, which is a 371 of PCT/US00/13048, filed 05/11/2000, which claims benefit of US Provisional Application No. 60/133,549, filed 05/11/1999.

Information Disclosure Statement

Applicant's information disclosure statement (IDS), filed on 10/22/2004, has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Response to Restriction Requirement

Acknowledgement is made of Applicant's election (without traverse) of Group I, claims 24-26, in a response filed 12/02/2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

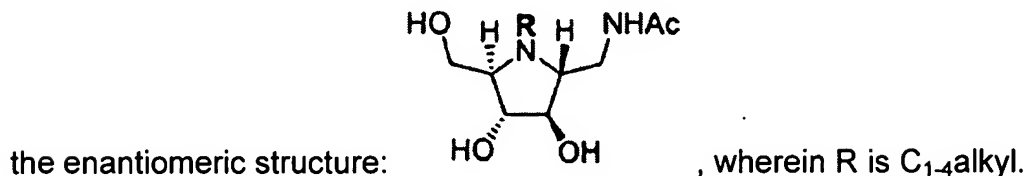
A person shall be entitled to a patent unless –

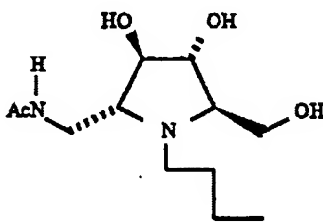
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Barta et al., US Pat. No. 5,663,342.

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Claim 24 is drawn to an inhibitor of hexoaminidase or glycosidase represented by



Barta et al. disclose the compound  as an inhibitor of glycosidase (see Ex. 51, col. 35, and col. 1, lines 13-15). The Barta et al. compound and disclosure meets every limitation of the instant claim 24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

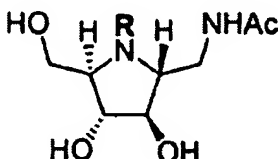
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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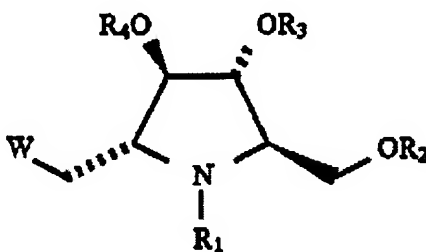
Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barta et al., US Pat. No. 5,663,342.

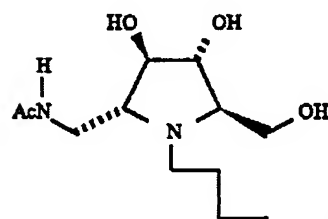
The instant application is drawn to an inhibitor of hexoaminidase or glycosidase

of the enantiomeric structure: , wherein R is C₁₋₄alkyl.

Determining the Scope and Content of the Prior Art

Barta et al. disclose compounds useful for inhibiting glycosidase enzymes of the

formula (III), , wherein R1 is methyl, ethyl, propyl, or n-butyl; R₂, R₃, and R₄ are each H; and W is (R₉R₁₀)(CO)O or R₁₀R₁₁N; R₁₀ is H; R₁₁ is R₉; and R₉ is alkyl (see col. 3, lines 5-15). Additionally, Barta et al. disclose the compound



as an inhibitor of glycosidase and lists it as a preferred embodiment of Formula (III) (see Ex. 51, col. 35, and col. 1, lines 13-15, and col. 3, lines 62-63).

Ascertaining the Differences Between the Prior Art and the Instant Application

The instant application claims an inhibitor of hexoaminidase or glycosidase, but the prior art only discloses the compound as an inhibitor of glycosidase.

The instant application claims a compound wherein NH is bonded to an acyl group, $-C(O)CH_3$. The prior art discloses compounds wherein the variable W of formula (III) is NH bonded to an acyl group, but does not define the variable W in that manner. Rather, W is defined to be $(R_9R_{10})(CO)O$ or $R_{10}R_{11}N$, which does not form an group HN-Ac. Nevertheless, the prior art discloses two compounds that contain HN-Ac groups and Example 51 is considered a preferred embodiment of compounds of formula (III) (see col. 35, ex. 50-51 and col. 3, lines 62-63).

Finding Prima Facie Obviousness

Barta et al. discloses one specie claimed in the instant application and disclose other similar compounds that inhibit glycosidase enzymes. One of ordinary skill in the art would be motivated to produce the compounds of the instant application and use them as glycosidase inhibitors. As a result, claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barta et al., US Pat. No. 5,663,342.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-26 are drawn to an inhibitor of hexoaminidase or glycosidase represented by enantiomers. Claims 24-26 do not claim a method of inhibiting hexoaminidase or glycosidase, but products having those properties. An "inhibitor" is a process or a function of a compound rather than a property. A claim to a function or process must be a process claim rather than a product claim.

Claims 24-26 must be amended to claim the process of inhibiting hexoaminidase or glycosidase. Such a method claim would be, for example, "A method of inhibiting hexoaminidase comprising...[list the steps involved in the process]" Alternatively, if the invention is drawn to the compounds, then the claims should be amended to state, "A compound of the enantiomeric structure...[insert the compounds claimed or a general formula with specific definitions for all variables]."

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

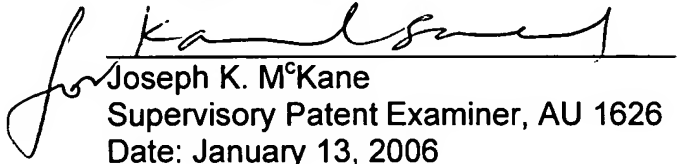
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Andrew B. Freistein
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Joseph K. McKane
Supervisory Patent Examiner, AU 1626
Date: January 13, 2006